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BioPlex® 2200 HSV-1 & HSV-2 IgG 510(k) Summary

510(k) Number K120959 Date Prepared: June 22, 2012

Introduction

Bio-Rad Laboratories hereby submits this 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This summary of 510(k) safety and effectiveness information provides detail as a basis for a determination of substantial equivalence for the BioPlex® 2200 HSV-1 & HSV-2 IgG kit.

Submitter name, address and contact

Submitter	Contact Person
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Device name

Product Trade Name: BioPlex® HSV-1 & HSV-2 IgG on the BioPlex® 2200 Multi-Analyte Detection System

Proprietary Name: BioPlex® 2200 HSV-1 & HSV-2 IgG

Classification Name:

enzyme linked immunosorbent assay, herpes simplex virus, hsv-1
enzyme linked immunosorbent assay, herpes simplex virus, hsv-2
calibrator, multi-analyte mixture
multi-analyte controls, all kinds (assayed)

Regulation Information

Product Code	Classification	Regulation Section	Panel
Enzyme linked immunosorbent assay, Herpes Simplex Virus, HSV-1 (MXJ)	Class II	21 CFR § 866.3305, Herpes simplex virus serological assays.	Microbiology
Enzyme linked immunosorbent assay, Herpes Simplex Virus, HSV-2 (MYF)	Class II	21 CFR § 866.3305, Herpes simplex virus serological assays.	Microbiology
Calibrator, multi-analyte mixture (JIX)	Class II	21 CFR § 862.1150 – Calibrator	Clinical Chemistry
Multi-Analyte Controls All kinds(assayed) (JJY)	Class I	21 CFR § 862.1660 – Quality control Material (Assayed and Unassayed)	Clinical Chemistry

Legally Marketed Predicate Device

BioPlex® 2200 HSV-1 & HSV-2 IgG Kit, k090409

INTENDED USE / INDICATIONS FOR USE

BioPlex® 2200 HSV-1 & HSV-2 IgG Kit

The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is a multiplex flow immunoassay intended for the qualitative detection and differentiation of IgG antibodies to herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) in human serum and EDTA or heparinized plasma. The test is indicated for sexually active individuals and expectant mothers as an aid for the presumptive diagnosis of HSV-1 or HSV-2 infection. The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for use in a pediatric population, neonates and immunocompromised patients or for use at point of care facilities.

The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is intended for use with the Bio-Rad BioPlex® 2200 System.

BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set

The BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set is intended for the calibration of the BioPlex® 2200 HSV-1 & HSV-2 IgG Reagent Pack.

BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set

The BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex® 2200 Instrument and BioPlex® HSV-1 & HSV-2 IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set has not been established with any other HSV-1 and HSV-2 antibody assays.

Kit Components

The BioPlex® 2200 HSV-1 & HSV-2 IgG Reagent Pack (665-3350). The reagent pack contains supplies sufficient for 100 tests.

Vial	Description
Bead Set	One (1) 10 mL vial, containing dyed beads coated with HSV-1 and HSV-2 antigen, an Internal Standard bead (ISB), a Serum Verification bead (SVB), and a Reagent Blank bead (RBB) in buffer with glycerol and protein stabilizers (bovine). ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (<0.1%) as preservatives.
Conjugate	One (1) 5 mL vial, containing phycoerythrin conjugated murine monoclonal anti-human IgG antibody and phycoerythrin conjugated murine monoclonal anti-human FXIII antibody, in buffer with protein stabilizers (bovine). ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (< 0.1%) as preservatives
Sample Diluent	One (1) 10 mL vial, containing buffer with protein stabilizers (bovine and murine). ProClin 300 (≤0.3%), sodium benzoate (≤0.1%) and sodium azide (< 0.1%) as preservatives.

Additional Required Items, Available from Bio-Rad:

Catalog #	Description
663-3300	BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set: Four (4) 0.5 mL vials, each containing human antibodies to HSV-1 and HSV-2 IgG derived from human disease state plasma, in a human serum matrix made from defibrinated plasma. All calibrators contain ProClin 300 (≤ 0.3%), sodium benzoate (≤0.1%) and sodium azide (< 0.1%) as preservatives
663-3330	BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set: Two (2) 1.5 mL Positive Control serum vials, each containing human antibodies to HSV-1 and HSV-2 IgG derived from human disease state plasma, in a human serum matrix made from defibrinated plasma. Two (2) 1.5 mL Negative Control serum vials, in a human serum matrix made from defibrinated plasma. All antibodies are derived from human disease state plasma. All controls contain ProClin 300 (≤ 0.3%), sodium benzoate (≤0.1%) and sodium azide (< 0.1%) as preservatives.
660-0817	BioPlex® 2200 Sheath Fluid: Two 4 L bottles containing Phosphate Buffered Saline (PBS). ProClin® 300 (0.03%) and sodium azide (<0.1%) as preservatives.
660-0818	BioPlex® 2200 Wash Solution: One 10 L bottle containing Phosphate Buffered Saline (PBS) and Tween 20. ProClin® 300 (0.03%) and sodium azide (<0.1%) as preservatives.
660-0000	BioPlex®2200 Instrument and Software System.

Device Description

The BioPlex® 2200 HSV-1 & HSV-2 IgG kit uses multiplex flow immunoassay, a methodology that greatly resembles traditional EIA, but permits simultaneous detection and identification of many antibodies in a single tube. Two (2) different populations of dyed beads are each coated with antigens associated with herpes simplex virus, types 1 and 2.

The BioPlex® 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel; the mixture is incubated at 37°C. After a wash cycle, anti-human IgG antibody, conjugated to phycoerythrin (PE), is added to the dyed beads, and this mixture is incubated at 37°C. The excess conjugate is removed in another wash cycle, and the beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached PE. Raw data are calculated in relative fluorescence intensity (RFI).

Three additional dyed beads, an Internal Standard Bead (ISB), a Serum Verification Bead (SVB) and a Reagent Blank Bead (RBB) are present in each reaction mixture to verify detector response, the addition of serum or plasma to the reaction vessel and the absence of

significant non-specific binding in serum or plasma. Refer to the BioPlex® 2200 System Operation Manual for more information.

The instrument is calibrated using a set of four (4) distinct calibrator vials, supplied separately by Bio-Rad Laboratories. The four (4) vials representing four (4) different antibody concentrations are used for calibration. The result for each of these antibodies is expressed as an antibody index (AI).

The BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set includes a negative control as well as multi-analyte positive control. The Positive Control is manufactured to give positive results, with values above the cut-off for each specific analyte. The Negative Control is manufactured to give negative results, with values below the cut-off for each specific analyte.

Technological Characteristics and Substantial Equivalence

The following tables summarize the similarities and differences between the modified BioPlex® 2200 HSV-1 & HSV-2 IgG kit and the predicate devices used in comparative studies.

Similarities

Item	Modified BioPlex® 2200 HSV-1 & HSV-2 IgG Kit	Predicate
Intended Use	The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is a multiplex flow immunoassay intended for the qualitative detection and differentiation of IgG antibodies to herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) in human serum and EDTA or heparinized plasma. The test is indicated for sexually active individuals and expectant mothers as an aid for the presumptive diagnosis of HSV-1 or HSV-2 infection. The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for use in a pediatric population, neonates and immunocompromised patients or for use at point of care facilities. The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is intended for use with the Bio-Rad BioPlex® 2200 System.	Same
Capture Antigen	1. gG1 glycoprotein (MW: 55 kD) 2. gG2 glycoprotein (MW: 31kD)	Same
Assay Type	Semi-Quantitative detection	Same
Specimen Type	Serum and plasma	Same
Cutoff	1.0 AI for HSV-1 and HSV-2 IgG assay	Same
Controls	Negative and Positive Controls	Same
Calibrator(s)	Multiple Calibrators	Same

Differences

The differences are to modify QC testing procedure from each reagent pack to once per day as stated in the Instructions For Use (IFU) of the BioPlex® 2200 HSV-1 & HSV-2 IgG and to add an additional 1 mg/mL of protein stabilizer and protease stabilizer in particle (bead) reagent.

Item	Modified BioPlex® 2200 HSV-1 & HSV-2 IgG Kit	Predicate
QC procedure	QC once per day and per new reagent pack lot	QC once per pack and per day
Bead Reagent	2 mg/mL protein stabilizer (bovine) and protease inhibitor in particle (bead) diluent	1 mg/mL protein stabilizer (bovine)

Other minor changes in the Instructions For Use are as follows.

- Change BioPlex Trademark from TM to ®
- Use new Warning symbol and text for "Irritant"
- Remove ProClin Trademark
- Add " ≤ " symbol for ProClin and sodium benzoate concentrations in Kit Components Section
- Revise the hazardous symbol in Precautions/Warning section in compliance with new EU regulation 2008/1272/EC and Global Harmonized System (GHS)

Summary of Design Control Activities

A Failure Mode and Effect Analysis (FMEA) was used to facilitate, capture, and quantify potential impacts of false positive or negative patient results. The Risk Priority Number (RPN) is a quantitative measure of the combined effects of severity, occurrence, and detection of potential risks. Specific mitigations are recommended that may include changes to the design or formulation if the RPN score exceeds a chosen threshold.

Based on the conclusion of the risk management report, the modified QC procedure fulfills the requirements of the specifications of the design control process. Therefore, the design control activities presented indicate that the modification of QC testing frequency provides an assay performance that is substantially equivalent to the current cleared kit

Performance Summary

A. Expected Values

Prevalence

The observed prevalence and expected values for the modified BioPlex® 2200 HSV-1 & HSV-2 IgG kit are presented in the tables below by age and gender for serum samples from sexually active individuals where an HSV-1 (N=200) and HSV-2 (N=200) tests were ordered.

Sexually Active Individuals with an HSV-1 Test Ordered (N=200):
Modified BioPlex® 2200 HSV-1 IgG

BioPlex® 2200 HSV-1 IgG								
Age in Years	**Gender**	**Positive**		**Equivocal**		**Negative**		**Total**
		N	**%**	**N**	**%**	**N**	**%**	**N**
18-20	**F**	4	80.0%	0	0.0%	1	20.0%	5
	M	6	60.0%	0	0.0%	4	40.0%	10
21-30	**F**	10	55.6%	0	0.0%	8	44.4%	18
	M	13	61.9%	0	0.0%	8	38.1%	21
31-40	**F**	17	94.4%	0	0.0%	1	5.6%	18
	M	15	75.0%	0	0.0%	5	25.0%	20
41-50	**F**	12	92.3%	0	0.0%	1	7.7%	13
	M	23	71.9%	0	0.0%	9	28.1%	32
51-60	**F**	8	72.7%	0	0.0%	3	27.3%	11
	M	16	72.7%	1	4.5%	5	22.7%	22
61-70	**F**	8	61.5%	0	0.0%	5	38.5%	13
	M	9	75.0%	0	0.0%	3	25.0%	12
71-80	**F**	0	0.0%	0	0.0%	1	100.0%	1
	M	2	100.0%	0	0.0%	0	0.0%	2
81-90	**F**	0	0.0%	0	0.0%	0	0.0%	0
	M	0	0.0%	0	0.0%	0	0.0%	0
Unknown	**Unknown**	1	50.0%	0	0.0%	1	50.0%	2
Total		144	72.0%	1	0.5%	55	27.5%	200

Sexually Active Individuals with an HSV-2 Test Ordered (N=200):
Modified BioPlex® 2200 HSV-2 IgG

BioPlex® 2200 HSV-2 IgG								
Age in Years	**Gender**	Positive		Equivocal		Negative		Total
		N	**%**	**N**	**%**	**N**	**%**	**N**
18-20	**F**	2	66.7%	0	0.0%	1	33.3%	3
	M	1	16.7%	0	0.0%	5	83.3%	6

21-30	**F**	5	26.3%	0	0.0%	14	73.7%	19
	M	13	38.2%	0	0.0%	21	61.8%	34
31-40	**F**	7	77.8%	0	0.0%	2	22.2%	9
	M	9	29.0%	0	0.0%	22	71.0%	31
41-50	**F**	6	66.7%	0	0.0%	3	33.3%	9
	M	15	42.9%	0	0.0%	20	57.1%	35
51-60	**F**	6	66.7%	0	0.0%	3	33.3%	9
	M	6	37.5%	0	0.0%	10	62.5%	16
61-70	**F**	4	50.0%	0	0.0%	4	50.0%	8
	M	3	20.0%	0	0.0%	12	80.0%	15
71-80	**F**	0	0.0%	0	0.0%	0	0.0%	0
	M	0	0.0%	0	0.0%	2	100.0%	2
81-90	**F**	0	0.0%	0	0.0%	1	100.0%	1
	M	0	0.0%	0	0.0%	0	0.0%	0
Unknown	**Unknown**	1	33.3%	0	0.0%	2	66.7%	3
Total		78	39.0%	0	0.0%	122	61.0%	200

B. Comparative Testing

Performance of the modified BioPlex® 2200 HSV-1 & HSV-2 IgG kit was tested against the predicate method for the populations from sexually active individuals where HSV-1 (N=200) and HSV-2 (N=200) test were ordered and a CDC HSV panel (N=80).

a. Sexually Active Individuals – HSV-1 and HSV-2 Test Ordered

Sexually Active Individuals With an HSV-1 Test Ordered:
Modified BioPlex® 2200 HSV-1 IgG vs. Predicate (N=399)

		BioPlex® 2200 HSV-1 IgG						
Sexually Active Individuals Test Ordered (N=399)		Positive	Equivocal	Negative	Total	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Total Agreement (95% CI)
Predicate	Positive	280	0	0	280	100% (280/280)	98.3% (116/118)	99.5% (396/398)
	Equivocal	1	1	0	2			
	Negative	0	1	116	117	98.6-100%	94.0 – 99.5%	98.2%-99.9%
	Total	281	2	116	399			

Sexually Active Individuals With an HSV-2 Test Ordered:
Modified BioPlex® 2200 HSV-2 IgG vs. Predicate (N=399)

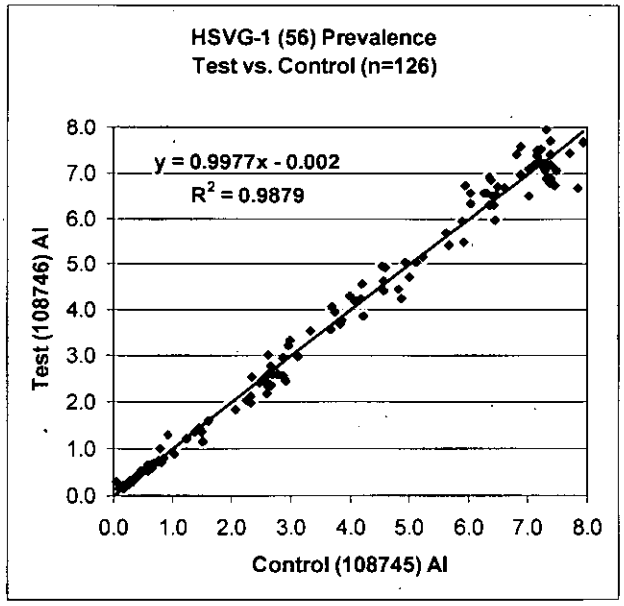
	Sexually Active Individuals Test Ordered (N=399)	BioPlex® 2200 HSV-2 IgG Positive	Equivocal	Negative	Total	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Total Agreement (95% CI)
Comparative Method	Positive	166	0	0	166	99.4% (166/167)	100% (232/232)	99.7% (398/394)
	Equivocal	0	0	1	1			
	Negative	0	0	232	232	96.7-99.9%	98.4-100%	98.6-100%
	Total	166	0	233	399			

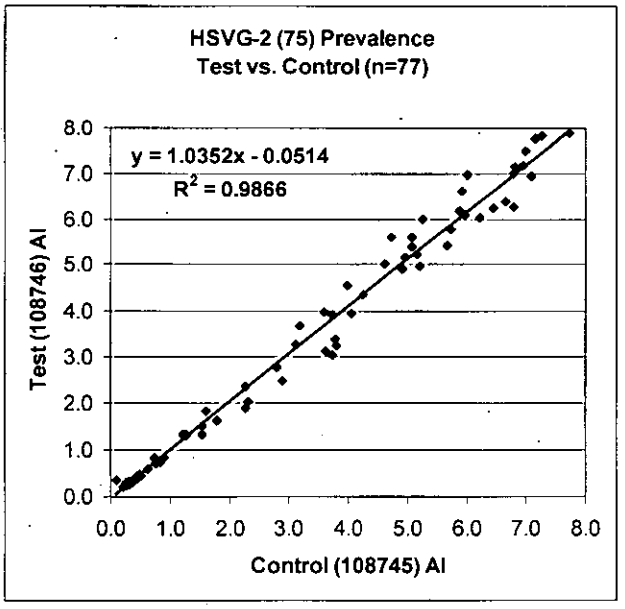
Comparison between modified and predicate devices

Linear regression analysis was performed using the results within the measuring range to compare the modified and predicate assays. Scatter plots along with regression statistics (slope, intercept, and correlation (R^2)) of are presented below.

Statistics of regression analysis

BioPlex Assay	Slope	Intercept	Correlation (R^2)
HSV-1	0.9977	-0.002	0.9879
HSV-2	1.0352	-0.0514	0.9866





b. CDC HSV Panel (N=80): The performance was assessed using a well characterized HSV serum panel from the CDC.

CDC HSV Panel: Modified BioPlex® 2200 HSV-1 IgG vs. CDC (N=80)

CDC HSV Panel (N=80)		BioPlex® 2200 HSV-1 IgG						
		Positive	Equivocal	Negative	Total	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Total Agreement (95% CI)
CDC HSV-1 Result	Positive	42	0	0	42	100.0% (42/42)	97.4% (37/38)	98.8% (79/80)
	Negative	0	1	37	38			
	Total	42	1	37	80	91.6 – 100%	86.5– 99.5%	93.3- 99.8%

CDC HSV Panel: Modified BioPlex® 2200 HSV-2 IgG vs. CDC (N=80)

CDC HSV Panel (N=80)		BioPlex® 2200 HSV-2 IgG						
		Positive	Equivocal	Negative	Total	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Total Agreement (95% CI)
CDC HSV-2 Result	Positive	40	0	0	40	100.0% (40/40)	100.0% (40/40)	100.0% (80/80)
	Negative	0	0	40	40			
	Total	40	0	40	80	91.2 – 100%	91.2– 100%	95.4- 100%

C. Precision Studies

A precision panel, consisting of 8 panel members for each analyte, was prepared by Bio-Rad Laboratories. For each analyte, 2 had high positive, 2 had low positive, 2 had antibody levels near the cutoff, and 2 high negative panel members.

Precision testing was performed at Bio-Rad Laboratories on one lot of the modified BioPlex® 2200 HSV-1 & HSV-2 IgG kit. Each of the 8 panel members was tested in duplicate on 2 runs per days for 5 days for a total of 20 results per panel member (2 replicates x 2 runs x 5 days = 20 replicates per panel member). The data were analyzed for intra-assay and inter-

assay precision in accordance to the CLSI EP5-A2 guideline. The standard deviation (SD) and percent coefficient of variation (%CV) were calculated. Results are shown in below.

Serum Precision- Modified BioPlex® 2200 HSV-1 IgG

HSV-1 IgG Panel Members	BioPlex® 2200 HSV-1 IgG									
	Sample N	Mean AI	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Negative	20	0.5	0.02	4.5%	0.00	0.0%	0.00	0.0%	0.02	4.5%
High Negative	20	0.7	0.04	5.5%	0.04	5.5%	0.00	0.0%	0.05	7.8%
Near Cutoff	20	1.0	0.06	5.9%	0.06	5.9%	0.00	0.0%	0.08	8.4%
Near Cutoff	20	1.0	0.05	5.0%	0.00	0.0%	0.00	0.0%	0.05	5.0%
Low Positive	20	1.3	0.06	4.9%	0.05	3.8%	0.00	0.0%	0.08	6.2%
Low Positive	20	1.6	0.13	8.0%	0.05	3.1%	0.09	5.6%	0.16	10.3%
High Positive	20	3.1	0.17	5.4%	0.00	0.0%	0.08	2.6%	0.19	6.0%
High Positive	20	3.4	0.22	6.4%	0.00	0.0%	0.14	4.1%	0.26	7.6%

Serum Precision- Modified BioPlex® 2200 HSV-2 IgG Serum

HSV-2 IgG Panel Members	BioPlex® 2200 HSV-2 IgG									
	Sample N	Mean AI	Within Run		Between Run		Between Day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Negative	20	0.6	0.04	6.5%	0.00	0.0%	0.00	0.0%	0.04	6.5%
High Negative	20	0.8	0.04	5.6%	0.04	4.8%	0.00	0.0%	0.06	7.4%
Near Cutoff	20	1.1	0.06	5.4%	0.03	2.9%	0.02	1.6%	0.07	6.3%
Near Cutoff	20	1.1	0.05	5.0%	0.00	0.0%	0.00	0.0%	0.05	5.0%
Low Positive	20	1.3	0.06	4.6%	0.03	2.4%	0.01	0.6%	0.07	5.2%
Low Positive	20	2.3	0.13	5.8%	0.08	3.4%	0.00	0.0%	0.15	6.7%
High Positive	20	4.1	0.21	5.2%	0.07	1.7%	0.14	3.3%	0.26	6.4%
High Positive	20	4.7	0.17	3.5%	0.08	1.7%	0.05	1.1%	0.19	4.1%

Comparison of precision between modified and predicate devices is shown below.

HSV-1 IgG Precision Comparison Summary: Modified vs. Predicate devices

HSV-1 IgG	Mean, AI		Within Run %CV		Total Precision %CV		Between Run %CV		Between Day %CV	
Panel Members	Predicate	Modified	Predicate	Modified	Predicate	Modified	Predicate	Modified	Predicate	Modified
High Negative	0.5	0.5	6.3%	4.5%	6.3%	4.5%	0.0%	0.0%	0.0%	0.0%
High Negative	0.7	0.7	6.4%	5.5%	7.6%	7.8%	0.0%	5.5%	4.1%	0.0%
Near Cutoff	1.0	1.0	7.1%	5.9%	7.7%	8.4%	3.2%	5.9%	0.0%	0.0%
Near Cutoff	1.0	1.0	5.0%	5.0%	6.9%	5.0%	3.2%	0.0%	3.5%	0.0%
Low Positive	1.3	1.3	6.9%	4.9%	8.6%	6.2%	3.0%	3.8%	4.3%	0.0%
Low Positive	1.7	1.6	8.0%	8.0%	10.1%	10.3%	6.0%	3.1%	1.0%	5.6%
High Positive	3.2	3.1	4.1%	5.4%	4.3%	6.0%	1.2%	0.0%	0.0%	2.6%
High Positive	3.6	3.4	6.0%	6.4%	6.4%	7.6%	2.2%	0.0%	0.0%	4.1%

HSV-2 IgG Precision Comparison Summary: Modified vs. Predicate devices

HSV-2 IgG	Mean, AI		Within Run %CV		Total Precision %CV		Between Run %CV		Between Day %CV	
Panel Members	Predicate	Modified	Predicate	Modified	Predicate	Modified	Predicate	Modified	Predicate	Modified
High Negative	0.7	0.6	6.4%	6.5%	7.8%	6.5%	4.5%	0.0%	0.0%	0.0%
High Negative	0.8	0.8	6.3%	5.6%	7.4%	7.4%	4.0%	4.8%	0.0%	0.0%
Near Cutoff	1.1	1.1	4.1%	5.4%	5.2%	6.3%	2.0%	2.9%	2.6%	1.6%
Near Cutoff	1.2	1.1	4.9%	5.0%	4.9%	5.0%	0.0%	0.0%	0.0%	0.0%
Low Positive	1.3	1.3	7.7%	4.6%	9.8%	5.2%	2.4%	2.4%	5.6%	0.6%
Low Positive	2.4	2.3	6.3%	5.8%	6.8%	6.7%	2.6%	3.4%	0.0%	0.0%
High Positive	4.4	4.1	6.1%	5.2%	6.1%	6.4%	0.0%	1.7%	0.0%	3.3%
High Negative	4.8	4.7	3.7%	3.5%	3.7%	4.1%	0.0%	1.7%	0.0%	1.1%

D. Interference

Testing for interfering substances was conducted according to CLSI EP7-A2. Samples were prepared by blending a pool of negative human serum with samples positive for HSV-1 and HSV-2 IgG to achieve values of 2.0 to 3.0 AI and interferent or solvent (negative control) was added exogenously at levels indicated below. Test and control samples were evaluated in replicates of ten using the modified BioPlex® 2200 HSV-1 & HSV-2 IgG Kits.

Interference Substances

Substance	**Concentration**
Hemoglobin	500 mg/dL
Bilirubin (unconjugated)	20 mg/dL
Bilirubin (conjugated)	30 mg/dL
Cholesterol	500 mg/dL
Red Blood Cells	0.4% (v/v)

Substance	Concentration
Gamma-Globulin	6 g/dL
Triglycerides	3300 mg/dL
Total Protein (albumin)	12 g/dL
Beta-Carotene	0.6 mg/dL
Ascorbic Acid	3 mg/dL
Lithium Heparin	8000 units/dL
Sodium Heparin	8000 units/dL
EDTA	800 mg/dL
Sodium Citrate	1000 mg/dL

E. Matrix Comparison

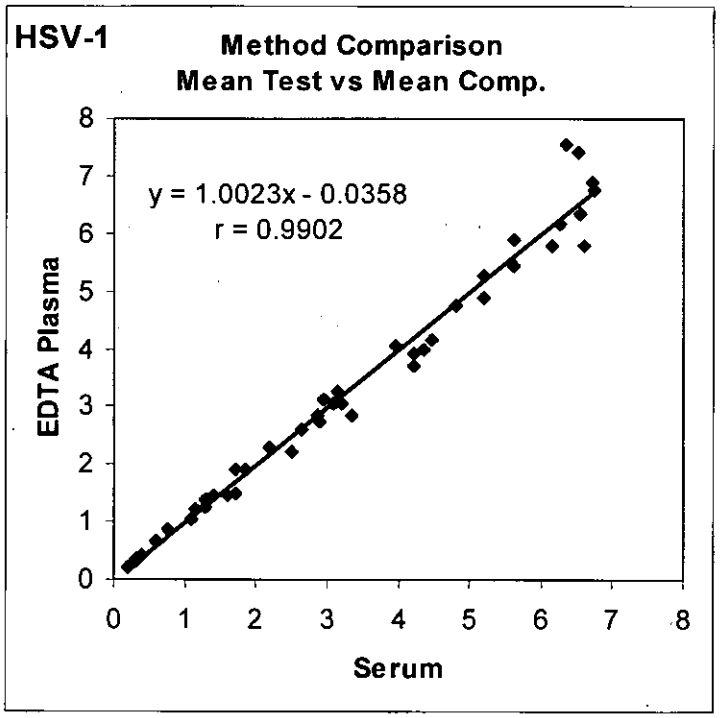
Matched serum and plasma (EDTA and heparin sodium) samples drawn from the same donor were acquired from commercial sources. For each assay in the panel more than 40 samples were collected within the measurement range of the assay. Samples were assayed in replicates of two using the modified BioPlex® 2200 HSV-1 & HSV-2 IgG kits. Mean plasma AI values were compared to matched mean serum AI values. The regression correlation parameters for the slopes, intercepts and correlation coefficient (r) are shown below

Matrix Comparison Regression Statistics

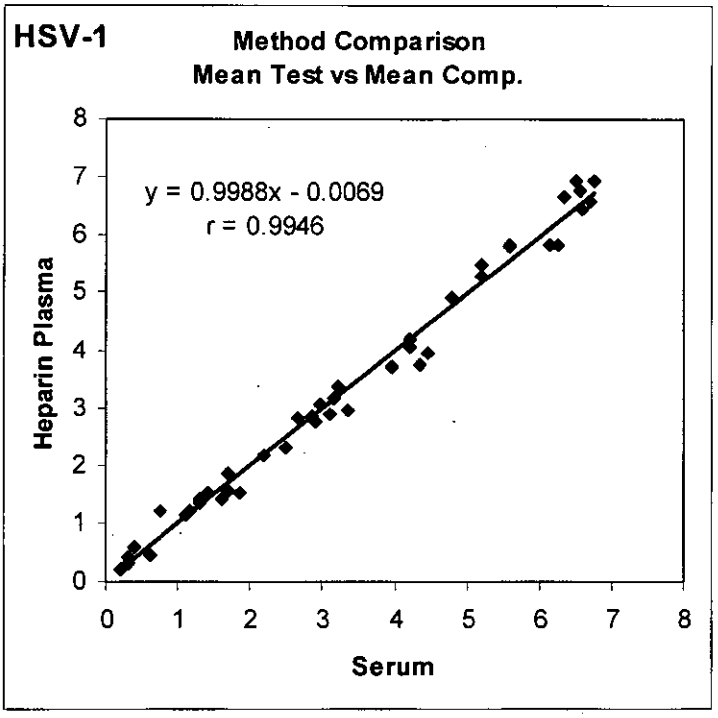
BioPlex Assay	Matrix	N	Slope	Intercept	Correlation (r)
HSV-1	EDTA vs. Serum	47	1.0023	-0.0358	0.9902
HSV-1	Heparin vs. Serum	47	0.9988	-0.0069	0.9946
HSV-2	EDTA vs. Serum	44	0.9945	-0.0737	0.9945
HSV-2	Heparin vs. Serum	44	0.9523	0.0649	0.9946

Scatter plots comparing the performance of EDTA and heparin plasma samples against serum samples are shown below.

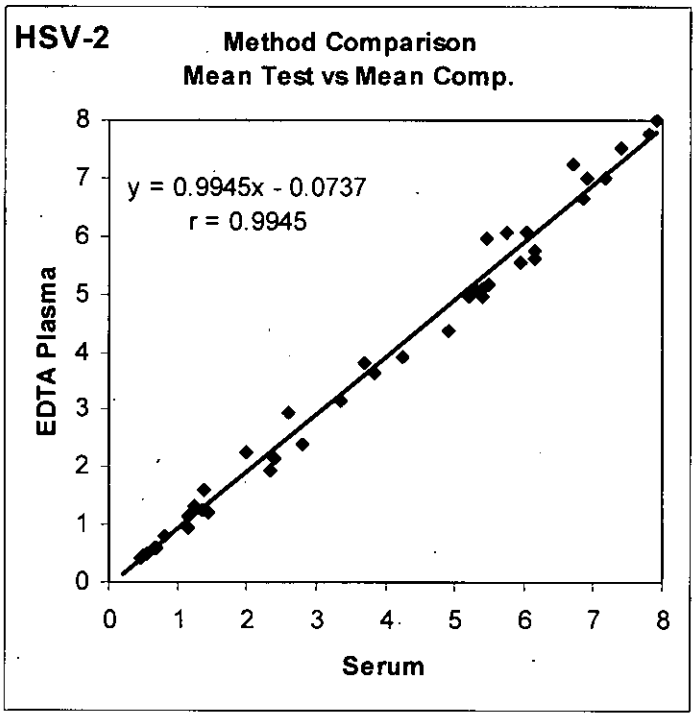
HSV-1: EDTA Plasma vs. Serum (N=47)



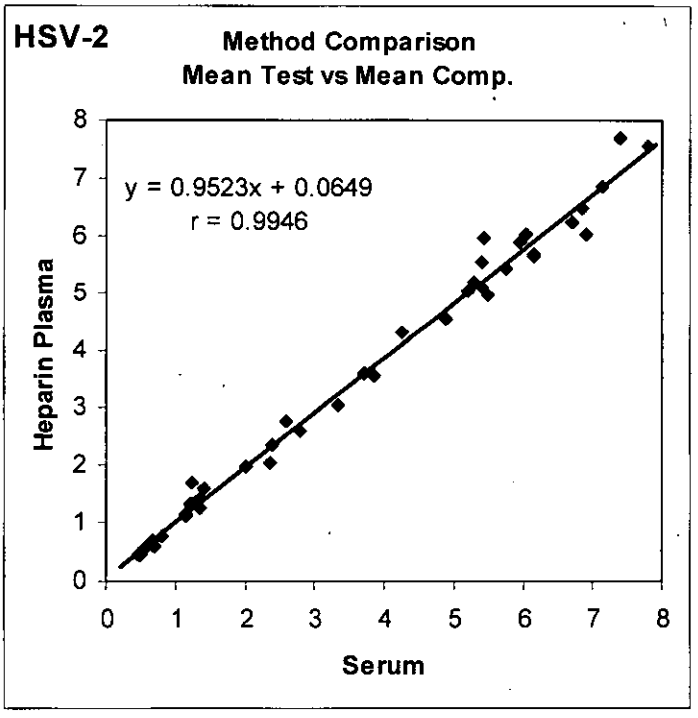
HSV-1: Heparin Plasma vs. Serum (N=47)



HSV-2: EDTA Plasma vs. Serum (N=44)



HSV-2: Heparin Plasma vs. Serum (N=44)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 22 2012

Bio-Rad Laboratories, Inc.
c/o Mr. Juang Wang
BioPlex Division
5500 E. Second Street
Benicia, CA 94510

Re: K120959
Trade/Device Name: BioPlex 2200 HSV-1 & HSV-2 IgG Kit on the
BioPlex 2200 Multi-analyte Detection System
BioPlex 2200 HSV-1 & HSV-2 IgG Calibrator Set
BioPlex 2200 HSV-1 & HSV-2 IgG Control Set
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Serological Reagents
Regulatory Class: Class II
Product Code: MXJ, MYF, JIX, JJY
Dated: March 28, 2012
Received: March 30, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication(s) For Use Statement

510(k) Number (if known): K120959

Device Name: BioPlex® 2200 HSV-1 & HSV-2 IgG Kit
BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set
BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set

Indications for Use:

BioPlex® 2200 HSV-1 & HSV-2 IgG Kit

The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is a multiplex flow immunoassay intended for the qualitative detection and differentiation of IgG antibodies to herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) in human serum and EDTA or heparinized plasma. The test is indicated for sexually active individuals and expectant mothers as an aid for the presumptive diagnosis of HSV-1 or HSV-2 infection. The predictive value of positive or negative results depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2.

The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for use in a pediatric population, neonates and immunocompromised patients or for use at point of care facilities.

The BioPlex® 2200 HSV-1 & HSV-2 IgG kit is intended for use with the Bio-Rad BioPlex® 2200 System.

BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set

The BioPlex® 2200 HSV-1 & HSV-2 IgG Calibrator Set is intended for the calibration of the BioPlex® 2200 HSV-1 & HSV-2 IgG Reagent Pack.

BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set

The BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex® 2200 Instrument and BioPlex® 2200 HSV-1 & HSV-2 IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex® 2200 HSV-1 & HSV-2 IgG Control Set has not been established with any other HSV-1 and HSV-2 antibody assays.

Prescription Use _X_ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-Continue on another page if needed)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Tamara Feldblum
Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety